

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2003 list were published in the Federal Register in April 2003.

New Approvals

ANADA Number: 200-314

Pioneer Product: 035-805
Trade Name: PennchlorS 700™
Ingredients: Chlortetracycline, sulfamethazine
Sponsor: Pennfield Oil Company
Approval Date: January 29, 2003
Status: Over-the-counter
Route: Oral, via feed
Species: Beef cattle
Drug Form: Type A Medicated Article to make two-way combination Type C medicated feed.
Concentration: Chlortetracycline – 35 grams chlortetracycline hydrochloride activity per pound of Type A Medicated Article; Sulfamethazine – 35 grams of sulfamethazine activity per pound of Type A Medicated Article
Indications: As an aid in the maintenance of weight gains in the presence of respiratory disease such as shipping fever.
Tolerance: 21CFR 556.150 Chlortetracycline: Tolerances are established for the sum of tetracycline residues in the tissues of beef cattle of 2 parts per million in muscle, 6 parts per million in liver, and 12 parts per million in fat and kidney.
21CFR 556.670 Sulfamethazine: A tolerance of 0.1 part per million is established for negligible residues of sulfamethazine in the uncooked edible tissues of cattle.
Withdrawal: 7 days

21CFR 558.140

ANADA Number: 200-322

Pioneer Product: 135-780
Trade Name: Butorphanol Tartrate Injection
Ingredients: Butorphanol tartrate
Sponsor: Phoenix Scientific, Inc.
Approval Date: January 22, 2003
Status: Prescription only
Route: Intravenous
Species: Horses
Drug Form: Liquid (solution)
Concentration: 10 milligrams per milliliter
Indications: For relief of post partum pain, and pain associated with colic.

21CFR 522.246

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Supplemental Approvals

NADA Number: 141-203

This supplemental application provides for the control of pain and inflammation associated with osteoarthritis.

Trade Name: Deramaxx™ Chewable Tablets
Ingredients: Deracoxib
Sponsor: Novartis Animal Health US, Inc.
Approval Date: February 11, 2003
Status: Prescription only
Route: Oral
Species: Dogs
Drug Form: Tablets (chewable)
Concentration: 25 and 100 milligrams per tablet
Indications: For the control of pain and inflammation associated with osteoarthritis, and for the control of postoperative pain and inflammation associated with orthopedic surgery in dogs weighing at least 4 pounds.
Patent Number: 5,521,207 Expiration Date: November 30, 2013
Exclusivity: 3 years

21CFR 520.538

NADA Number: 141-007

This supplemental application provides for the addition of a larger tablet size (strength).

Trade Name: Drontal® Plus Tablets
Ingredients: Praziquantel, pyrantel pamoate, febantel
Sponsor: Bayer Corp.
Approval Date: February 10, 2003
Status: Prescription only
Route: Oral
Species: Dogs
Drug Form: Tablet
Concentration: 136 mg praziquantel, 136 mg pyrantel base, and 680.4 mg febantel per tablet
Indications: For the removal of tapeworms (*Dipylidium caninum*, *Taenia pisiformis*, *Echinococcus granulosus*, and removal and control of *Echinococcus multilocularis*), hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*), ascarids (*Toxocara canis* and *Toxascaris leonina*), and whipworms (*Trichuris vulpis*).
Patent Number: 5,036,069 Expiration date: July 30, 2008

21CFR 520.1872

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Change of Sponsor

NADA Number:	034-393	040-264	041-541	044-016
	046-209	049-934	099-150	

From: Aventis Animal Nutrition, Inc.

To: Merial Ltd.
3239 Satellite Blvd., Bldg. 500
Duluth, GA 30096-4640
Drug labeler code: 050604

Removal of Patent Number

NADA Numbers: 141-053, 141-111

Patent Number: 6,013,808

Expiration Date: April 15, 2019

Suitability Petition Action

Number:	02P-0470/CP1
Sponsor:	Karen A. Sisson
Petition:	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Eqvalan [®] , Merial Ltd., NADA 134-314, by the following characteristics: the generic product will consist of a different dosage form (granule/crumble) from the pioneer.
Action:	Approved on April 17, 2003.

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